

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of:

Enrofloxacin for Poultry: Withdrawal
of Approval of Bayer Corporation's
New Animal Drug Application
(NADA) 140-828 (Baytril)

FDA DOCKET: 00N-1571

DATE: July 26, 2002

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The Center for Veterinary Medicine's Response to Bayer's June 24, 2002, Request for Production of Documents

The Center for Veterinary Medicine ("the Center" or "CVM") submits the following Response to Bayer's June 24, 2002 Request for Production of Documents to CVM. The Center objects generally to Bayer's Request for Production of Documents as unduly burdensome. Specifically, CVM objects to Instruction No. 2, which requests information about withheld documents. There is no requirement in 21 C.F.R. Part 12 for CVM to provide an index of withheld documents.

Further, CVM specifically objects to Request No. 1 as being overly broad and unduly burdensome. Request No. 1 asks for all documents referred to in CVM's Response to Bayer's Interrogatories to CVM. The documents supporting CVM's Responses to Bayer's June 24, 2002, Interrogatories are contained in Docket No. 00N-1571. Nothing in 21 C.F.R. Part 12 requires the Center to submit a cross-index to documents supporting its Response to Interrogatories.

00N-1571

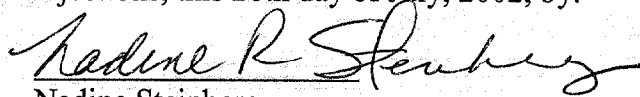
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Further Bayer notes that the document responsive to Bayer's Request No. 16 has already been submitted to Docket No. 00N-1571 and, pursuant to Bayer's instructions, has not been resubmitted in response to this Request.

CVM also notes that it has forwarded this Request for Production of Documents to certain of its witnesses in the Enrofloxacin Hearing, who may have responsive documents. CVM is producing responsive documents already received. CVM is aware that certain witnesses are continuing to search their files for responsive documents. If CVM obtains any responsive documents from these witnesses after this Response is filed, CVM will submit a supplemental Response and will promptly provide those documents to Bayer and to Docket No. 00N-1571.

Notwithstanding the general and specific objections noted above, CVM submits the attached documents in response to Bayer's Requests.

Respectfully submitted, with objections, this 26th day of July, 2002, by:

A handwritten signature in cursive script, appearing to read "Nadine R. Steinberg".

Nadine Steinberg
Counsel for the Center for Veterinary Medicine
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
(301) 827-5050

CERTIFICATE OF SERVICE

I hereby certify that an original and one copy of the foregoing Center for Veterinary Medicine's Response to Bayer's June 24, 2002, Request for Production of Documents was hand delivered this 26th day of July, 2002, to:

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852

I also certify that a copy of the pleading (without attachments) has been hand delivered and e-mailed, this 26th day of July, 2002, to:

The Office of the Administrative Law Judge (ddavidso@oc.fda.gov)
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

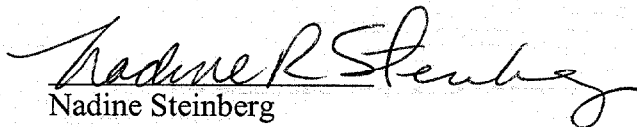
I also certify that a copy of the pleading (without an attachment) was e-mailed and mailed by first class mail, postage prepaid, and a copy of the entire Response was hand delivered, this 26th day of July, 2002, to:

Robert B. Nicholas (rnicholas@mwe.com)
McDermott, Will & Emery
600 13th Street, NW
Washington, DC 20005

and

Kent D. McClure (KmcClure@ahi.org)
Animal Health Institute
1325 G Street, NW, Suite 700
Washington, DC 20005

Dated: 7/26/02


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